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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,595	08/06/2001	Irena Slage	A7949	9500

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EXAMINER	
SALAD, ABDULLAHI ELMI	
ART UNIT	**PAPER NUMBER**
2157	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,595	SLAGE ET AL.	
	Examiner	Art Unit	
	Salad E. Abdullahi	2157	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-27 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-27 and 35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/2006 has been entered.

2. Applicant's argument with respect claims 1, 2, 4-27 and 35-39 have been fully considered but are moot in view of new grounds of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 1 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown U.S. Patent No. 6,381,577[hereinafter Brown] in view of Herren et al., U.S. Patent No. 6,108,635 [Herren].

As per claim 1, Brown discloses data management method, comprising:

Providing a data engine(server 18)(see fig. 1);

obtaining first observation automatically recorded by a data sampling device (monitoring device 28) (measuring glucose or blood pressure) (see col. 6, lines 26-41);

and a second observation manually recorded by a user (responses to the queries by the user) (see col. 6, line 66 to col. 7, line 7), said first and said second observation defining plurality of different observations, said plurality of different observation relating to data of an identical subject (physiological condition of a patient) (see col. 6, line 26-35);

sending said plurality of different observations to said data engine (see col. 6, lines 26-31);

storing said plurality of different observations database under control of said data engine (see fig. 2 and col. 6, lines 42-50); and

in response to a report request:

retrieving said plurality different observations from said database in accordance with parameters in said report request provide plurality of a retrieved observations (see col. 10, lines 62 to col. 11, line 4); and

producing a report based on said plurality of retrieved observations(see col. 10, lines 62 to col. 11, line 4).

Brown is silent regarding: wherein the plurality of observations relate to a data of identical subject matter and are not obtained in response to a query.

Herren discloses in an analogous art discloses a clinical data gathering system for collecting observation relate to data of identical subject matter and are not obtained in response to a query (see figs. 3 and 4 and col. 7, lines 32-48 and col. 8, lines 19-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention presented with teaching of Brown to incorporate the remote data collection mechanism such as storing plurality of observations relate to a data of

identical subject matter and are not obtained in response to a query as taught by Herren to make easy the collection, storing and analyzing related clinical data from remotely users.

As per claim 37-38 Herren discloses the data management as set forth in claim 1 further providing a plurality of modules adapted to communicate said plurality of different observations to said data engine (see fig. 2 and col. 6, lines 42-50).

As per claim 35, the claim includes features discussed above with respect to claim 2, further reciting.

providing a plurality of modules adapted to communicate said plurality of different observations to said data engine (see fig. 2 and col. 6, lines 42-50);

As per claim 36, Herren discloses the method of providing a data management server as set forth in claim 35, wherein the selected ones of the plurality of modules include a module adapted to handle processing at the server for clients that provide an observation, relating to the given subject, from a remote data source comprising a database (see col. 6, lines 42-50).

As per claim 39, Herren discloses the data management method as set forth in claim 1, further comprising obtaining from a remote database source a third observation relating

to said subject the remote data source being a remote database (see fig. 2 and col. 10, line 31 to col. 11line 6).

5. Claims 2, 14-15 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harren et al., U.S. Patent No. 6,108,635 in view of Brown.

As per claim 2, and 14-15, Harren discloses clinical trial data management server method comprising:

receiving, at server(Integrated Disease Information System 10), a user profile (patient information) provided by a client(see fig. 2 and col. 10, lines 49-63);

based on said user profile, indicating to said client one or more matching clinical trials (col. 10, lines 49-63), receiving a clinical trial selection from said client (col. 10, lines 49-63);

providing to said client a selected clinical trial module (clinical trial module 14) indicated by said clinical trial selection and corresponding a selected one of said matching clinical trials (col. 29, lines 20-60);

the modules being adapted to obtain clinical trial data including a respective data observation(see col. 28, lines 60-67 and col. 29, lines 20-60).

Harren is silent regarding:

receiving at said server said respective data observations;

storing said respective data observation in a database of data observations;

and in response to a report request:

retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of retrieved observations and producing a report based on said plurality of retrieved observations.

Brown in an analogous art discloses a multi-user monitoring system including:

receiving at said server said respective data observations (see fig. 2 and col. 6, lines 42-50);

storing said respective data observation in a database of data observations(see fig. 2 and col. 6, lines 42-50); and

in response to a report request:

retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of retrieved observations (see col. 10, lines 62 to col. 11, line 4);and

producing a report based on said plurality of retrieved observations(see col. 10, lines 62 to col. 11, line 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the teaching of Brown into system of Harren to enable dynamic monitoring and collection of healthcare information of respective patients.

As per claims 26-27, the claim include features similar to those of claim 14-15, thus claims 26-27are rejected same rational as claim 14-15.

6. Claims 4-13, 16-19 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harren and brown as applied to claim 2 and further in view of Linder.

As per claim 4, Harren discloses substantial features of the claimed invention as discussed above with respect to claim

Harren is silent regarding: wherein said clinical trial data is provided to said server by a medical device.

Linder discloses a data management server for receiving medical data provided the said server by medical device (see fig. 1 and col. 3, lines 42-61). Therefore, it would have been obvious to one having ordinary skill in the art at time of the invention to incorporate the teachings of Linder such as wherein said clinical trial data is provided to said server by a medical device such that accurate clinical trial information can be matched and provided to the respected user (see col. 28, lines 60-67 and col. 29, lines 20-60).

As per claim 5, Linder discloses the data management server method as set forth claim 3, wherein said clinical trial data is provided to said server over the Internet (see fig. 2).

As per claim 6-7, Linder discloses the data management server method as set forth in claim 3, wherein said clinical trial data is provided to said server by general-purpose computing device having said clinical trial data manually inputted by a user (see fig. 1 and col. 4, lines 14-43).

As per claim 8-9, Herren discloses the clinical trial data management server method as set forth in claim 3 wherein:

said server includes a data engine (see fig.2 and col. 10, lines 49-63)

said data engine comprises a health data management module (10) (see fig.2 and col. 10, lines 49-63);

and a clinical trials management module(see fig.2 and col. 10, lines 49-63);

said health data management module comprises data analysis algorithms used by said data engine to analyze said clinical trial data(see fig.2 and col. 10, lines 49-63) and

said clinical trials management module: selects said one more matching clinical trials, based on said user profile(see fig.2 and col. 10, lines 49-63);

provides an approval of said clinical trial selection(see col. 28, lines 60-67 and col. 29, lines 20-60);

and provides said selected clinical trial module(see col. 28, lines 60-67 and col. 29, lines 20-60).

As per claim 10-13, Linder discloses the data management server method as set forth in claim 8, wherein said health data management module comprises data analysis algorithms and adapted to accept data for one or more cardiology data, diabetes data, allergy data, and immunology data (see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20).

As per claim 16, Herren discloses substantial features of the claimed invention as discussed above with respect to claim 15,

Murphy is silent regarding: said data engine is adapted to receive said clinical trial data from a medical device.

Linder discloses a data management server for receiving medical data provided the said server by medical device (see fig. 1 and col. 3, lines 42-61). Therefore, it would have been obvious to one having ordinary skill in the art at time of the invention to incorporate the teachings of Linder such as wherein said clinical trial data is provided to said server by a medical device such that accurate clinical trial information can be matched and provided to the respected user to ensure the health of the user.

As per 17, Linder discloses the clinical trial data server as set forth in claim 16 wherein said data engine adapted clinical trial data over the Internet(see fig. 1).

As per claim 18-19, Linder discloses the clinical data server as set forth in claim 15, wherein said data engine is adapted receive said clinical trial data from a general-purpose computing device(see fig. 1 and col. 4, lines 14-43).

As per claim 20-25, Linder discloses the clinical trial data server as set forth in claim 15 wherein:

said health data management module comprises data analysis algorithms used by said data engine analyze said clinical trial data(see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20); and

said clinical trials management module:

selects said one based on said user profile(see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20);

provides an approval of said clinical trial selection(see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20);

and provides said selected clinical trial module more matching clinical trials (see fig. 5 and col. 7, lines 55-66 and col. 8, line 66 to col. 9, line 20).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salad E Abdullahi whose telephone number is 571-272-4009. The examiner can normally be reached on 8:30 - 5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ario Etienne can be reached on 571-272-4001. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300.**

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ABDULLAHI SALAD
PRIMARY EXAMINER

Abdullahi Salad
Primary Examiner
2/16/2006